NVLAP (logo)	**DEPARTMENT OF COMMERCE** National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	**ISSUE DATE:** February 22, 2016
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		LAP: Healthcare IT LAP

SUBJECT: Addition of the 2015 Edition Certification Criteria for EHR Technology to the HIT LAP

The 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Records (EHR) Definition, and ONC Health IT Certification Program Modifications; final rule was published in the *Federal Register* on October 16, 2015. The Office of the National Coordinator (ONC) affirmed this rule as building on previous rules with a continued "focus on the establishment of an interoperable nationwide health information infrastructure." This focus "enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications."

The 2015 Edition Test Method approved by ONC includes test procedures, test tools and test data and is published on the ONC website at < https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method>.

Based on this rule and the approved Test Method, NVLAP has updated its Healthcare Information Technology (HIT) Laboratory Accreditation Program (LAP) to include the 2015 EHR certification criteria for testing of health information technology capabilities. The following method has been added into the available test methods in the HIT LAP:

> 31/2015   Testing based on criteria in 45 CFR Part 170, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule (October 16, 2015) including all criteria except: §170.315(c)(1) through (c)(4) and (f)(5).

For laboratories currently accredited in the NVLAP HIT LAP, addition of testing to the 2015 certification criteria to the scope of accreditation must be requested in writing (e-mail is a sufficient form of written request). With the written request, each applicant must also supply:

- a description of how 2015 testing has been added into its management system as well as any updated management system documents to support this incorporation,
- a current list of key staff, including all testers authorized to perform HIT testing in the laboratory,
- a description of how competency of the testers to 2015 testing has been evaluated and confirmed, and
- the documented evidence of competence of the testers (e.g. training records).

Once this information is received, NVLAP will proceed with a review of the information. If this information is determined to be complete, a remote assessment (e.g. teleconference call and/or

webinar) will be scheduled with the laboratory to assess the competency of the testers approved to conduct testing associated with this scope addition.

Please note that costs associated with this remote assessment will be billed to the laboratory. A report of the assessment will be issued in accordance with Clauses 3.3.2.1 (a) through (e) of NIST Handbook 150. Any nonconformity cited will require resolution per Clause 3.3.3 of NIST Handbook 150.

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